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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/728,463	10/10/96	LONBERG	N 14643-009020

HM12/0912  
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EXAMINER	
DECLOUX, A	
ART UNIT	PAPER NUMBER

1644  
DATE MAILED: 09/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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# Office Action Summary

Application No.  
**08/728,463**

Applicant(s)  
**Lonberg et al.**

Examiner  
**DeCloux, Amy**

Group Art Unit  
**1644**



☒ Responsive to communication(s) filed on Apr 17, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-9, 13-17, 22-29, 37, 40, 50, 51, and 53 is/are pending in the applicat

Of the above, claim(s) 1-9 and 15-17 is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 13, 14, 22-29, 37, 40, 50, 51, and 53 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

### DETAILED ACTION

1. The request filed 7/17/00 (Paper No. 23) for a continued Prosecution Application (CPA) under 37 CFR 1.53.(d) based on parent application No. 08/728463 is acceptable and a CPA has been established. An action on the CPA follows.
2. The Art Unit location and the examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed according to the last paragraph of this office action.
3. Applicant's amendment, filed 7/17/00 (Paper No. 24), is acknowledged. Claims 10, 12, 18-21, 31-36, 38, 39, 41-49 and 52 have been canceled. Claims 11 and 30 have been canceled previously. Claims 13, 14, 22-29, 37, 40, 50, 51 and 53 have been amended.
4. Non-elected claims 1-9, and 15-17 are held to be withdrawn from further consideration under 37 CFR 1.142(b) as acknowledged in the parent application Serial No. 08/728,463. Claims 13, 14, 22-29, 37, 40, 50, 51 and 53 are being acted upon presently.
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).
6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. In particular, on page 38 of the instant specification, lines 16, 17 and 18 contain 4 sequences which are not identified by a SEQ ID tag. Furthermore, on page 163 of the instant specification, lines 24 and 25 contain 2 sequences which are not identified by a SEQ ID tag. Furthermore on page 254-256, SEQ ID NO:s 1-10 do not agree with SEQ ID NO:s 1-10 of the CRF and paper copy submitted with the CRF.

7. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 13-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 13-14 are drawn to a human immunoglobulin comprising a variable region having an amino acid sequence as set forth in SEQ ID NO:s 1,2,3,4,5,6,7,8,9 or 10, or 61-62. However, the specification does not enable one of skill in the art to make and use said immunoglobulin molecule with a variable region that is no longer than 6 amino acids according to SEQ ID NO:s 1-10 or 61-62 of the submitted CRF. Janeway et al teach that the V gene segment typically makes up 95-101 amino acids (see page 3:13 of Immunobiology, Third Edition, 1997). Therefore it is not clear from the instant sequences how a variable region could be made up of such a small segment as encompassed by SEQ ID NO:s 1, 2, 3, 4, 5, 6, 7, 8, 9 or 10 or 61-62. Furthermore, it is not clear which full length immunoglobulins containing the above mentioned sequences will be able to bind CD4.

9. Claims 13, 14, 22-29, 37, 40, 50, 51 and 53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody that specifically binds human CD4 or an antigenic fragment thereof comprising the disclosed heavy and light chains of clone 1E11, comprising the disclosed heavy and light chains of clone 1G2, comprising the disclosed heavy and light chains of clone 6G5, comprising the disclosed heavy and light chains of clone 10C5, and comprising the disclosed heavy and light chains of clone 4D1, does not reasonably provide enablement for the broader recitation of a monoclonal human immunoglobulin comprising a single chain that specifically binds human CD4 or an antigenic fragment thereof " as recited in the instant claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed in claims 13, 14, 22-29, 37, 40, 50, 51 and 53 without an undue amount of experimentation. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the

extremely large number of combinations of heavy and light chains that must be tested in order to enable specific binding to human CD4 or an antigenic fragment thereof. The instant claims are drawn to a human monoclonal immunoglobulin that specifically binds human CD4. However Janeway teaches that the association of different heavy and light chain variable regions form the antigen binding site (see page 3:21, last paragraph). Therefore it is not clear that any of the single immunoglobulins recited in the instant claims will by themselves bind specifically to CD4 or antigenic fragments thereof, and it would take undue experimentation to determine the sequence of the second chain that would be necessary to form the antigen binding structure, with the exception of the pairs of immunoglobulin heavy and light chains denoted by clones 1E11, 1G2, 6G5, 10C5 or 4D1 as disclosed in the instant specification.

In view of the quantity of experimentation necessary to use the claimed invention, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

11. Claims 13 and 14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

A) Claim 13 and dependent claim 14 are indefinite in their recitation of "an amino acid sequence encoded by a nucleic acid with a sequence set forth in SEQ ID NO:1....SEQ ID NO:10" because the recited sequences encompass both nucleic acid sequences (SEQ ID NO:s 1, and 7-10) and amino acid sequences (SEQ ID NO:s 2-6) according to the submitted CRF.

12. No claim is allowed.

13. It is noted that the references associated with PTO 1449 were not available to the examiner in the instant application or in the parent application 08/352,322, and can not be found. Therefore, the current examiner respectfully asks that the documents listed on the 1449 forms be sent to the examiner for consideration.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-

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5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.  
Patent Examiner,  
September 11, 2000

*David A. Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182 / 644